

**Form PTO-1449 Modified**

List of Patent and Publications  
Cited by Applicant  
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U.S. Department of Commerce  
Patent and Trademark Office

Docket No.  
**KLI-0002**

Serial No.  
**09/801,470**

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Applicant  
**Kliman et al.**

JUN 26 2003

Filing Date  
**March 8, 2001**

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

PN	AA	Anderson, T. et al., "Stage specific alterations in the apical membrane glycoproteins on endometrial epithelial cells related to implantation in rabbits", <i>Biol Reprod.</i> , 1986, 34:701-720
	AB	Bamberger, A-M. et al., "Strongly reduced expression of the cell cycle inhibitor p27 in endometrial neoplasia", <i>Virchows Arch.</i> , 1999, 434:423-28
	AC	Beresford, S. et al., "Risk of endometrial cancer in relation to use of oestrogen combined with cyclic progestagen therapy in postmenopausal women", <i>The Lancet</i> , 1997, 349:458-461
	AD	Bergh, P., "The impact of embryonic development and endometrial maturity on the timing of implantation", <i>Fertil Steril.</i> , 1992, 58(3):537-542
	AE	Blasco, L., "Dyssynchrony in the maturation of endometrial glands and stroma", <i>Fertil. Steril.</i> , 1994, 61(4):596-7
	AF	Burger, C. et al., "Hormone replacement therapy in women treated for gynaecological malignancy", <i>Maturitas</i> , 1999, 32:69-76
	AG	Bush, T., "Evidence for primary and secondary prevention of coronary artery disease in women taking oestrogen replacement therapy", <i>Eur. Heart J.</i> , 1996, 17(Supplement D):9-14
	AH	Castelbaum, A., "Timing of the endometrial biopsy may be critical for the accurate diagnosis of luteal phase deficiency", <i>Fertil Steril.</i> , 61(3):443-447
	AI	Castellsague J., "Recent epidemiological studies of the association between hormone replacement therapy and venous thromboembolism", <i>Drug Safety</i> , 1998, 18(2):117-23
	AJ	Collaborative Group on Hormonal Factors in Breast Cancer. "Breast cancer and hormone replacement therapy: collaborative reanalysis of data from 51 epidemiological studies of 52 705 women with breast cancer and 108 411 women without breast cancer", <i>The Lancet</i> , 1997, 350:1047-1059.
	AK	Creus, M. et al., "Integrin expression in normal and out-of-phase endometria", <i>Hum. Reprod.</i> , 1998, 13(12):3460-3468
PN	AL	Design of the women's health initiative clinical trial and observational study, The women's health initiative study group, <i>Control Clin Trials</i> , 1998, 19:61-109

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DATE CONSIDERED

7/15/03

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**1641****JUN 26 2003****TECH CENTER 1600/2900****OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

<b>PN</b>	<b>AM</b>	Dockery, P. et al., "Changes in nuclear morphology in the human endometrial glandular epithelium in women with unexplained infertility", <i>Hum Reprod</i> , 1996, 11(10):2251-2256
	<b>AN</b>	Enders, A. et al., "Surface coats of the mouse blastocyst and the uterus during the preimplantation period", <i>Anat. Rec.</i> , 1974, 180:31-46
	<b>AO</b>	Giangrande, P. et al., "The opposing transcriptional activities of the two isoforms of the human progesterone receptor are due to differential cofactor binding", <i>Mol. Cell Biol.</i> , 2000, 20(9):3102-3115
	<b>AP</b>	Gibson, M., et al., "Error in histologic dating of secretory endometrium: variance component analysis", <i>Fertil Steril.</i> , 1991, 56(2):242-247
	<b>AQ</b>	Grodstein, F. et al., "Postmenopausal hormone therapy and mortality", <i>N Engl J Med</i> , 1997, 336(25):1769-1775
	<b>AR</b>	Gurpide, E. et al., "Introduction: research on the human endometrium", <i>Ann New York Acad Sci.</i> , 1990, 622:1-5
	<b>AS</b>	Hamel, P. et al., "G1 cyclins and control of the cell division cycle in normal and transformed cells", <i>Cancer Investigation</i> , 1997, 15(2):143-152
	<b>AT</b>	Hendrickson, M. et al., "Surgical pathology of the uterine corpus", <i>Major Problems Pathology</i> , 1980, 12:36-98
	<b>AU</b>	Hewitt, K. et al., "Disappearance of anionic sites from the surface of the rat endometrial epithelium at the time of blastocyst implantation", <i>Biol Reprod</i> , 1979, 21:691-707
	<b>AV</b>	Johannisson, E. et al., "Endometrial morphology and peripheral hormone levels in women with regular menstrual cycles", <i>Fertil Steril.</i> , 1987, 48(3):401-408
	<b>AW</b>	Johannisson, E. et al., "Morphometric analysis of the human endometrium in relation to peripheral hormone levels", <i>Fertil Steril.</i> , 1982, 38(5):564-571
<b>✓</b>	<b>AX</b>	Kakar, F. et al., "Non-contraceptive estrogen use and risk of gallstone disease in women", <i>Am J Public Health</i> , 1988, 78(5):564-566

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Group **1644**  
**TECH CENTER 1600/2900**

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

PN	AY	Keller, C. et al., "Supplemental and complementary alternatives to hormone replacement therapy", <i>J of Amer Acad Nurse Pract.</i> , 1999, 11(5):187-198
	AZ	Kliman H. et al., "MAG mucin expression abnormalities in natural cycle biopsies predict subsequent IVF failure", Society for Reproductive Medicine, 1997, Cincinnati (Abstr.)
J	BA	Kliman, H. et al., "Absence of biochemical or morphologic markers of endometrial glandular development in a mock cycle predicts pregnancy failure in a subsequent donor oocyte transfer cycle", American Society for Reproductive Medicine, 1998, San Francisco. (Abstr.)
~	BB	Kliman, H. et al., "A mucin-like glycoprotein identified by MAG (mouse ascites golgi) antibodies", <i>Am J Pathol</i> , 1995, 146(1):166-181
	BC	Kumar, N. et al., "Selective down-regulation of progesterone receptor isoform B in poorly differentiated human endometrial cancer cells: Implications for unopposed estrogen action", <i>Cancer Research</i> , 1998, 58:1860-1865
	BD	Kurman, R. et al., "Endometrial hyperplasia and related cellular changes" in Blaustein's pathology of the female genital tract, Ed: Kurman RJ. Springer-Verlag, New York, pp. 411-437
	BE	Kwon, T. et al., "Overexpression of cyclin E and cyclin-dependent kinase inhibitors (p27 Kip1): Effect on cell cycle regulation in HeLa cells", <i>Biochem and Biophys Research Comm.</i> , 1997, 238:534-538
	BF	Leslie, K. et al., "Differential expression of the A and B isoforms of progesterone receptor in human endometrial cancer cells", <i>Ann New York Acad. Sci.</i> , 1997, 828:17-26
	BG	Lessey, B. et al., "Integrins as markers of uterine receptivity in women with primary unexplained infertility", <i>Fertil Steril.</i> , 1995, 63(3):535-542
	BH	Lessey, B. et al., "Aberrant integrin expression in the endometrium of women with endometriosis", <i>J Clin Endocrinol Metab.</i> , 1994, 79(2):643-649
↓	BI	Lessey, B. et al., "Integrin adhesion molecules in the human endometrium. Correlation with the normal and abnormal menstrual cycle", <i>J Clin Invest.</i> , 1992, 90:188-195

EXAMINER

PN

DATE CONSIDERED 7/15/03

<b>Form PTO-1449 Modified</b>		Docket No. <b>KLI-0002</b>	Serial No. <b>09/801,470</b>
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		JUN 26 2003	
U.S. Department of Commerce Patent and Trademark Office		Filing Date <b>March 8, 2001</b>	Group <b>TECH CENTER 1600/2900</b> <del>1641</del> <b>1644</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
<b>PN</b>	<b>BJ</b>	Li, T-C. et al., "A quantitative study of endometrial development in the luteal phase: comparison between women with unexplained infertility and normal fertility", <i>Brit J Ob Gyn.</i> , 1990, 97:576-582	
	<b>BK</b>	Li, T-C. et al., "How precise is histologic dating of endometrium using the standard dating criteria?", <i>Fertil Steril.</i> , 1989, 51(5):759-763	
	<b>BL</b>	Li, T-C. et al., "A new method of histologic dating of human endometrium in the luteal phase", <i>Fertil Steril.</i> , 1988, 50(1):52-60	
	<b>BM</b>	Lloyd, R. et al., "p27 <sup>kip1</sup> : A multifunctional cyclin-dependent kinase inhibitor with prognostic significance in human cancers", <i>Am J Pathol.</i> , 1999, 154(2):313-323	
	<b>BN</b>	Meyer, W. et al., "Hydrosalpinges adversely affect markers of endometrial receptivity", <i>Human Reproduction</i> , 1997, 12(7):1393-1398	
*	<b>BO</b>	Mishell, D.R., Davajan, V., and Lobo, R.A., 1991, Infertility, contraception and reproductive endocrinology, Blackwell Scientific Publications	
	<b>BP</b>	Morgan, D. et al., "Cyclin-dependent kinases: engines, clocks, and microprocessors", <i>Annu Rev Cell Dev Biol.</i> , 1997, 13:261-291	
	<b>BQ</b>	Mosher, W., "Infertility: why business is booming", <i>Am Demograph</i> , 1987, 9:42-43	
	<b>BR</b>	Mote, P. et al., "Colocalization of progesterone receptors A and B by dual immunofluorescent histochemistry in human endometrium during the menstrual cycle", <i>J. Clin. Endocrinol. Metab.</i> , 1999, 84(8):2963-2971	
	<b>BS</b>	Musgrove, E. et al., "Cell cycle control by steroid hormones", <i>Sem Cancer Biol.</i> , 1994, 5:381-389	
	<b>BT</b>	Musgrove, E. et al., "Mechanisms of cyclin-dependent kinase inactivation by progestins", <i>Mol Cell Biol</i> , 1998, 18(4):1812-1825	
	<b>BU</b>	Navot, D. et al., "The window of embryo transfer and the efficiency of human conception in vitro", <i>Fertil Steril.</i> , 1991, 55(1):114-118	
✓	<b>BV</b>	Noyes, R., "Uniformity of secretory endometrium: study of multiple sections from 100 uteri removed at operation", <i>Fertil Steril.</i> , 1956, 7:103-109	
<b>EXAMINER</b> <b>PN</b>		<b>DATE CONSIDERED</b> <b>7/15/03</b>	

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		Filing Date <b>March 8, 2001</b>	
U.S. Department of Commerce Patent and Trademark Office		Group <b>1641 1644</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
<b>PN</b>	<b>BW</b>	Noyes, R. et al., "Accuracy of endometrial dating", <i>Fertil Steril.</i> , 1953, 4(6):504-517	
	<b>BX</b>	Noyes, R. et al., "Dating the endometrial biopsy", <i>Fertil Steril.</i> , 1950, 1(1):3-25	
	<b>BY</b>	Orend, G., "Cytoplasmic displacement of cyclin E-CDK2 inhibitors p21Cip1 and p27Kip1 in anchorage- independent cells", <i>Oncogene</i> , 1998, 16:2575-2583	
	<b>BZ</b>	Ovulation Drugs, A Guide for Patients. American Society for Reproductive Medicine, 2000, 1209 Montgomery Highway, Birmingham AL 35216-9822	
	<b>CA</b>	Pedersen, T., "Statin trials and goals of cholesterol-lowering therapy after AMI", <i>Am Heart J</i> , 1999; 138(2 Pt 2):177-82	
	<b>CB</b>	Pike, M. et al., "Estrogen-progestin replacement therapy and endometrial cancer", <i>J Natl Cancer Inst</i> , 1997, 89(15):1110-1116	
	<b>CC</b>	Reid, I., "Pharmacological management of osteoporosis in postmenopausal women: a comparative review", <i>Drugs Aging</i> , 1999;15(5):349-363	
	<b>CD</b>	Reynisdóttir, I. et al., "The subcellular locations of p15 <sup>ink4b</sup> and p27 <sup>Kip1</sup> coordinate their inhibitory interactions with CDK4 and CDK2", <i>Genes Dev.</i> , 1997, 11:492-503	
	<b>CE</b>	Rosano, G. et al., "Cardiovascular pharmacology of hormone replacement therapy", <i>Drugs Aging</i> , 1999,15(3):219-234	
	<b>CF</b>	Rozenberg, S. et al., "Osteoporosis Management", <i>Int J Fertil Womens Med</i> , 1999, 44(5):241-249	
	<b>CG</b>	Ross, R. et al., "Effect of hormone replacement therapy on breast cancer risk: estrogen versus estrogen plus progestin", <i>J Natl Cancer Inst.</i> , 2000, 92(4):328-332	
	<b>CH</b>	Rossouw, J., "Hormone replacement therapy and cardiovascular disease", <i>Curr Opin Lipidol.</i> , 1999, 10:429-434	
✓	<b>CI</b>	Satyaswaroop, P. et al., "Isolation and culture of human endometrial glands", <i>J Clin Endocrinol Metab.</i> , 1979, 48(4):639-641	
<b>EXAMINER</b> <i>Patricia J. MR</i>		<b>DATE CONSIDERED</b> <i>7/15/03</i>	

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JUN 26 2003

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		Applicant <b>Kliman et al.</b>	
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
<b>PN</b>	<b>CJ</b>	Schairer, C. et al., "Menopausal estrogen and estrogen-progestin replacement therapy and breast cancer risk", <i>JAMA</i> , 2000, 283(4):485-491	
	<b>CK</b>	Scharbo-Dehaan, M., "Hormone replacement therapy", <i>Nurse Pract.</i> 1996, 21(12 Pt 2):1-13	
	<b>CL</b>	Schatz, F. et al., "Studies on human endometrial cells in primary culture", <i>Ann New York Acad Sci.</i> , 1991, 622:80-88	
	<b>CM</b>	Schneider, D. et al., "Timing of postmenopausal estrogen for optimal bone mineral density: the Rancho Bernardo Study", <i>JAMA</i> , 1997, 277(7):543-547	
	<b>CN</b>	Scott, R. et al., "The effect of interobserver variation in dating endometrial histology on the diagnosis of luteal phase defects", <i>Fertil Steril.</i> , 1988, 50(6): 888-892	
	<b>CO</b>	Seifert, M. et al., "Estrogen replacement therapy in women with a history of breast cancer", <i>Maturitas</i> , 1999, 32:63-68	
	<b>CP</b>	Sheaff, R. et al., "Cyclin E-CDK2 is a regulator of p27 <sup>Kip1</sup> ", <i>Genes Devel.</i> , 1997, 11:1464-1478	
	<b>CQ</b>	Shiozawa, T. et al., "Relationship between the expression of cyclins/cyclin-dependent kinases and sex- steroid receptors/Ki67 in normal human endometrial glands and stroma during the menstrual cycle", <i>Mol Hum Reprod.</i> , 2(10):745-752	
	<b>CR</b>	Shiozawa, T. et al., "Involvement of cyclin-dependent kinase inhibitor p27 <sup>Kip1</sup> in growth inhibition of endometrium in the secretory phase and of hyperplastic endometrium treated with progesterone", <i>Mol Hum Reprod.</i> , 4(9):899-905	
	<b>CS</b>	Singh, S. et al., "Loss or altered subcellular localization of p27 in Barrett's associated adenocarcinoma", <i>Cancer Res.</i> , 1998, 58:1730-1735	
	<b>CT</b>	Smith, S. et al., "Endometrial biopsy dating: interobserver variation and its impact on clinical practice", <i>J Repro Med.</i> , 1995, 40(1): 1-3	
<b>*</b>	<b>CU</b>	Society for assisted reproductive technology 1997 national report, 1999, Centers for Disease Control, Atlanta, GA (The report can be accessed at the Centers for Disease Control's web site at: <a href="http://www.cdc.gov/ncdd/php/drh/art97/pdf/art97.pdf">http://www.cdc.gov/ncdd/php/drh/art97/pdf/art97.pdf</a> which is the direct cite to the PDF file)	
EXAMINER <b>PN</b>		DATE CONSIDERED <b>7/15/07</b>	

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		Filing Date <b>March 8, 2001</b>	Group <b>1641</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
<b>PV</b>	<b>CV</b>	Soucek, T. et al., "Inactivation of the cyclin-dependent kinase inhibitor p27 upon loss of the tuberous sclerosis complex gene-2", <i>Proc Natl Acad Sci.USA</i> , 1998, 95:15653-15658	
	<b>CW</b>	Tang, M-X. et al., "Effect of oestrogen during menopause on risk and age at onset of Alzheimer's disease", <i>The Lancet</i> , 1996, 348(9025):429-432	
	<b>CX</b>	Tavani, A. et al., "The adverse effects of hormone replacement therapy", <i>Drugs Aging</i> , 1999, 14(5):347-357	
	<b>CY</b>	Taylor, H. et al., "HOXA10 is expressed in response to sex steroids at the time of implantation in the human endometrium", <i>J Clin Invest.</i> , 1998, 101(7):1379-1384	
	<b>CZ</b>	Third Party Reproduction, A Guide for Patients. American Society for Reproductive Medicine. 1996. 1209 Montgomery Highway, Birmingham AL 35216-9822	
	<b>DA</b>	Treloar, A. et al., "Variation of the human menstrual cycle through reproductive life", <i>Internat J Fertil.</i> , 1967, 12(1, pt. 2):77-126.	
	<b>DB</b>	Vassilopoulou-Sellin et al., "Estrogen replacement therapy after localized breast cancer: clinical outcome of 319 women followed prospectively", <i>J Clin Oncol</i> , 1999, 17(5):1482-1487	
	<b>DC</b>	Vassilopoulou-Sellin et al., "Randomized prospective trial of estrogen-replacement therapy in women with a history of breast cancer", <i>J of Natl Cancer Inst Monog.</i> , 1994, 16:153-159	
	<b>DD</b>	Wang, H. et al., "Progesterone receptor subtype B is differentially regulated in human endometrial stroma", <i>Mol. Hum. Reprod.</i> , 1998, 4(4):407-412	
*	<b>DE</b>	Yen, S.S.C., Jaffe, R.B., and Barbieri, R.L., 1999, Reproductive endocrinology: physiology, pathophysiology, and clinical management. W.B. Saunders Company	
<b>EXAMINER</b> <b>PV</b>		<b>DATE CONSIDERED</b> <b>7/15/03</b>	

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<i>PN</i>	<b>DF</b>	5,599,680	02/04/97	Feinberg et al.	435	7.21

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation YES NO	

**EXAMINER***PN***DATE CONSIDERED** *7/15/03*